510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, Daig Division, Inc.
Address:	14901 DeVeau Place
	Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 351-1496
Fax Number:	(952) 930 - 9481
Contact Person:	Jennifer Nevison
Date Submission Prepared:	September 24, 2004

B. Device Information

Trade Name:	Agilis™ Steerable Catheter Introducer
Common or Usual Name:	Steerable Transseptal Catheter Introducer
Classification Name:	Catheter Introducer (per 21CFR 870.1340)
Predicate Devices:	Fast-Cath™ (Two-Piece AMAS) Transseptal & Intra-Cardiac Catheter Introducers (K964518 & K973840)
Device Description:	The Agilis™ Steerable Catheter Introducer set consists of a dilator, guidewire, and steerable sheath, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation, and a radiopaque tip marker to improve fluoroscopic visualization. The device is provided sterile and is intended for single-use only.
Intended Use:	The SJM Agilis™ Steerable Catheter Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Agilis™ Steerable Catheter Introducer are substantially equivalent to the predicate devices including product design, packaging, sterilization, and labeling. Where dimensional and material differences exist between the proposed device and the predicate devices, mechanical and biocompatibility testing demonstrated that these differences do not adversely affect safety and effectiveness.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division, Inc. considers the Agilis™ Steerable Catheter Introducer to be substantially equivalent to the predicate device, Fast-Cath™ (Two-Piece AMAS) Transseptal Intra-Cardiac Catheter Introducer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2005

Mr. Glenn Jacques
Sr. Regulatory Affairs Specialist
St. Jude Medical, Daig Division, Inc.
14901 Deveau Place
Minnetonka, MN 55345

Re: K042623
Trade/Device Name: Agilis™ Steerable Catheter Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: II
Product Code: DYB
Dated: January 11, 2005
Received: January 13, 2005

Dear Mr. Jacques:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna P. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042623

Device Name: Agilis™ Steerable Catheter Introducer

Indications for Use:

The St. Jude Medical (SJM) Agilis™ Steerable Catheter Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Prescription Use X AND/OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042623